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10/069,107

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Andrew H Cragg

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06/07/2006

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/069,107 | CRAGG ET AL. | |
| | Examiner | Art Unit | |
| | Brian Szmal | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6 and 8-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-28 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 8-21, 23, 24, 29, 30, 33, 34 and 36-43 is/are rejected.
- 7) ☒ Claim(s) 22, 31, 32 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claim 12 is objected to because of the following informalities: In line 2, "15" should be removed. Appropriate correction is required.
2. Claims 19 and 20 are objected to because of the following informalities: "the extending control member" lacks antecedent basis. Appropriate correction is required.
3. Claim 33 is objected to because of the following informalities: "Claim 20" should read as "Claim 29". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5, 8, 11, 18-20, 24, 29, 30, 33, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenneman et al (5,645,566).

Brenneman et al disclose a means of sealing blood vessel punctures, and further disclose an elongated member with a distal end and a proximal end and a lumen extending therebetween; the lumen accommodating at least one extending member that enters the blood vessel through the puncture; the distal end comprising a tapered surface for receiving a portion of the blood vessel surrounding the puncture for impeding the distal end of the elongated member from entering the blood vessel; the elongated member has a constant outer diameter; the lumen is centered within the elongated

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member; the tapered surface at the distal end of the lumen has a conic shape; the outer diameter of the lumen at the distal end is about 50-99% of an outer diameter of the elongated member; the extending member extends beyond the distal end of the elongated member; the extending member includes a lumen that extends from the distal to proximal end; the extending member is configured to occlude and control a puncture in the blood vessel; the extending member is formed from a flexible material to prevent the extending member from catching on subcutaneous tissue as the extending member advances through the patient's skin and tissue at the puncture site; locating the puncture site by receiving a portion of a wall of the blood vessel with the distal end; the elongated member is advanced over a guidewire; the elongated member is introduced until an elastic recoil is produced by the blood vessel; the elastic recoil is felt by the operator; an outer diameter of the elongated member is larger than a diameter of the puncture of the blood vessel; and inserting a portion of an extending member into the blood vessel. See Figures 4a-4c, 4e and 4f; and Column 11, lines 4-55.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennehan et al (5,645,566).

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Regarding Claim 6, it would have been an obvious matter of design choice to place the lumen off-center along the longitudinal axis of the elongated member, since the Applicant does not disclose the criticality of the off-center placement of the lumen in relation to the disclosed centered placement of the lumen in the disclosure. Therefore, it would have been obvious to one of ordinary skill in the art that the centered lumen of Brenneman et al would be able to perform the same function as that of the claimed off-center lumen.

Regarding Claim 9, it would have been an obvious matter of design choice to have the tapered surface at the distal end of the lumen be a substantially concave spherical shape, since the Applicant has failed to disclose the criticality of the concave surface, in relation to a conic shape, such that the shape provides an advantage, used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious to one of ordinary skill in the art that the tapered surface of Brenneman et al would be capable of performing the same function as that of the claimed concave surface at the distal end of the lumen.

Regarding Claim 10, it would have been an obvious matter of design choice to have the tapered surface at the distal end of the lumen be a substantially stepped configuration, since the Applicant has failed to disclose the stepped configuration, in relation to other shapes, provides an advantage, used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious to one of ordinary skill in the art that the tapered surface of Brenneman et al would be capable of performing the same function as that of the claimed stepped configuration at the distal end of the lumen.

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8. Claims 3, 16, 17, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al (5,645,566) as applied to claims 1 and 29 above, and further in view of Cragg et al (6,162,192).

Brenneman et al, as discussed above, disclose a means of sealing blood vessel punctures, but fail to disclose the elongated member has an outer diameter which progressively decreases to a smaller diameter at the distal end; a depth indicating member positioned on an exterior of the elongated member and movable in an axial direction with respect to the elongated member; the depth indicating member is an elastic ring; a depth indicating member which is slidably movable in a longitudinal direction on the elongated member is set to mark a depth of the puncture in the blood vessel; and the extending member at least partially occludes the puncture in the blood vessel wall.

Cragg et al disclose a means of sealing a blood vessel puncture and further disclose the elongated member has an outer diameter which progressively decreases to a smaller diameter at the distal end; a depth indicating member positioned on an exterior of the elongated member and movable in an axial direction with respect to the elongated member; the depth indicating member is an elastic ring; a depth indicating member which is slidably movable in a longitudinal direction on the elongated member is set to mark a depth of the puncture in the blood vessel; and the extending member at least partially occludes the puncture in the blood vessel wall. See Column 3, lines 64-67; Column 4, lines 1-18; and Figure 2.

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Since both Brenneman et al and Cragg et al disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Brenneman et al to include the use of a depth indicator and a means to partially occlude the puncture, as per the teachings of Cragg et al, since it would provide a means of measuring the depth of the puncture as well as prevent any further blood loss.

9. Claims 12 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al (5,645,566) as applied to claim 1 above, and further in view of Janzen (5,437,631).

Brenneman et al, as discussed above, disclose a means of sealing a punctured blood vessel but fail to disclose the lumen at the distal end has a diameter of about 0.050 to 0.160 inches; and the extending member extends from the tapered surface of the device by about 0.10 to 6.0 inches.

Janzen discloses a percutaneous introducer set and means for sealing a puncture, and further discloses the lumen at the distal end has a diameter of about 0.050 to 0.160 inches; and the extending member extends from the tapered surface of the device by about 0.10 to 6.0 inches. See Figures 1 and 2; Column 6, lines 63-65; and Column 7, lines 11-20.

Since both Brenneman et al and Janzen disclose means for sealing a blood vessel puncture, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Brenneman et al to include the cited

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dimensions of Janzen, since it is well known in the art to utilize a percutaneous device with the claimed size ranges.

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al (5,645,566) as applied to claim 1 above, and further in view of Scribner (5,395,353).

Brenneman et al, as discussed above, disclose a means of sealing blood vessel punctures, but fail to disclose the elongated member is made of a material with a hardness of at least 50 D; a portion of the elongated member is made of a friction reducing material; and the elongated member is made of a friction reducing material. Scribner discloses a guiding catheter with controllable perfusion ports and further disclose the elongated member is made of a material with a hardness of at least 50 D; a portion of the elongated member is made of a friction reducing material; and the elongated member is made of a friction reducing material. See Column 7, lines 18-21. Since both Brenneman et al and Scribner disclose means for accessing blood vessels, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the disclosure of Brenneman et al to include the use of polyurethane as the material for the elongated member, as per the teachings of Scribner, since it is well known in the art that polyurethane has a hardness of at least 50 D and is also a low friction material.

11. Claims 21, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al (5,645,566) as applied to claims 19 and 29 above, and further in view of Tay et al (6,063,085).

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Brenneman et al, as discussed above, disclose means for sealing blood vessel punctures, but fail to disclose the distal end of the extending member has at least one vent hole for allowing fluid to enter the lumen of the extending member; blood from the vessel enters the extending member; and the blood entering the extending member provides visual feedback to the operator.

Tay et al disclose an apparatus for sealing vascular punctures, and further disclose the distal end of the extending member has at least one vent hole for allowing fluid to enter the lumen of the extending member; blood from the vessel enters the extending member; and the blood entering the extending member provides visual feedback to the operator. See Column 18, lines 15-25.

Since Brenneman et al and Tay et al disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Brenneman et al to include the use of a vent hole in the extending member, as per the teachings of Tay et al, since it would provide a visual indication to the operator of the depth from the incision to the puncture.

12. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al (5,645,566) in view of Tay et al (6,063,085).

Brenneman et al, as discussed above, disclosed above, disclose a means for sealing blood vessel punctures and further disclose introducing an elongated member through an incision, the elongated member comprising a distal end, a proximal end and a lumen extending therebetween, the lumen accommodating at least one inner member that enters the puncture in the blood vessel; and providing specific tactile feedback of the

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location of the blood vessel puncture by receiving an edge of the blood vessel surrounding the puncture in a tapered surface of the distal end of the elongated member which impedes entry of the elongated member through the puncture. See Figures 4a-4c, 4e and 4f; and Column 11, lines 4-55.

Brenneman et al however fail to disclose providing visual feedback of a general location of the blood vessel puncture by venting blood through an elongated member; and the visual feedback is provided by a control member at the distal end of the elongated member, the control member having a vent hole.

Tay et al, as discussed above, disclose a means for sealing blood vessel punctures, and further disclose providing visual feedback of a general location of the blood vessel puncture by venting blood through an elongated member; and the visual feedback is provided by a control member at the distal end of the elongated member, the control member having a vent hole. See Column 18, lines 15-25.

Since both Brenneman et al and Tay et al disclose means for sealing blood vessel punctures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Brenneman et al to include the use of providing visual feedback to the user, as per the teachings of Tay et al, since it would provide both visual and tactile feedback to the user to determine the placement of the blood vessel puncture.

Allowable Subject Matter

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13. Claims 22, 31, 32 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: Claims 25-28 are allowable since no prior art could be found teaching or suggesting a method for determining the depth of an incision comprising: the distal end includes a tapered surface for locating the blood vessel puncture site by capturing an edge of the blood vessel puncture and for impeding entry of the distal end of the elongated member into the vessel, as claimed in Claim 25.

Response to Arguments

15. Applicant's arguments with respect to claims 1-3, 5, 6, 8-21, 23, 24, 42 and 43 have been considered but are moot in view of the new ground(s) of rejection.

16. The indicated allowability of claims 29-41 is withdrawn in view of the newly discovered reference(s) to Brenneman et al, Cragg et al, and Tay et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone


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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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